UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/656,140	09/08/2003	Yuanxiang Tao	001107.00388	8826

22907 7590 06/12/2006

BANNER & WITCOFF
1001 G STREET N W
SUITE 1100
WASHINGTON, DC 20001

EXAMINER	
HILL, KEVIN KAI	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/656,140	TAO ET AL.	
	Examiner	Art Unit	
	Kevin K. Hill, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25,34,45-62 and 64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25,34,45-62 and 64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-25, 34, 62 and 64, drawn to a method of administering to a subject an effective amount of an agent which inhibits expression of PSD93 or PSD95, classified in class 514, subclass 44.

II. Claims 45-61, drawn to a method of screening for substances useful for relieving pain, classified in class 436, subclass 501.

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the purpose of Invention I is to decrease expression of either PSD93 or PSD95; whereas, the purpose of Invention II is to screen for substances that influence the ability of a first protein to interact with a second protein. Thus, the different inventions contain different method steps, are not disclosed as capable of use together, and are of materially different design and effect.

A reference rendering a method of administering to a subject an effective amount of an agent which inhibits expression of PSD95 as anticipated or obvious over the prior art would not necessarily also render a method of screening for substances useful for relieving pain as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one species does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

2. **Should Applicant elect Invention I, restriction to one of the following is also required under 35 USC 121.** Claim 1 contains an improper Markush Group that is not compliant with *In re Harnisch* and recites antisense oligonucleotides complementary to mRNAs

encoding different proteins, and thus form paragraph *M.P.E.P. 8.01 Election of Species* does not apply. Therefore, election is required of an antisense oligonucleotide complementary to an mRNA encoding, specifically:

i) PSD93, or

ii) PSD95.

The PSD93 and PSD95 proteins are structurally distinctly different amino acid sequences. Applicants are reminded that nucleic acid sequences encoding different proteins, and the amino acid sequences they encode, are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid and amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq.

A finding that PSD93 was novel and unobvious over the prior art would not necessarily extend to a finding that PSD95 was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one species does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed PSD93 or PSD95 protein consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Failure to elect a PSD93 or PSD95 protein consonant with Applicant's elected invention may result in a notice of non-responsive amendment.

Should Applicant elect Invention II, restriction to one of the following is also required under 35 USC 121. Claim 45 contains improper Markush Groups that are not compliant with *In re Harnisch* and recite first protein compositions and second protein compositions, and thus form paragraph *M.P.E.P. 8.01 Election of Species* does not apply.

Therefore, election is required of a first protein composition (one of (i)-(iii)) below and a second protein composition (one of (iv)-(viii)) below, specifically:

i) PSD93,

ii) PSD95,

iii) a combination of PSD93 and PSD95,

iv) nNOS,

v) NMDA receptor,

vi) NR2A subunit,

vii) NR2B subunit, or

viii) one specific combination of (iv)-(viii) above.

Claim 45 is generic to a genus of distinct and unrelated first protein permutations as well as a genus of distinct and unrelated second protein permutations. PSD93 and PSD95 are distinctly different genes encoding distinctly different proteins. Similarly, the genus of NMDA receptors comprise differing NR1 and NR2 subunit combinations, as represented in part by the NR2A and NR2B subunits, wherein each subunit is also encoded by a distinctly different gene. Applicants are reminded that nucleic acid sequences encoding different proteins, and the amino acid sequences they encode, are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleic acid and amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Furthermore, because each first and second protein is a distinctly different, non-identical molecular combination, a test substance that affects the binding of PSD93 to a NR2A subunit resulting in a unique physiological response, may have no effect on protein binding between PSD95 and nNOS and the physiological effect in response to said binding.

A reference rendering NMDA as anticipated or obvious over the prior art would not necessarily also render a combination of nNOS and NR2A as anticipated or obvious over the prior art. Similarly, a finding that PSD93 was novel and unobvious over the prior art would not necessarily extend to a finding that PSD95 was also novel and unobvious over the prior art.

Because these inventions are distinct for reasons given above, and because a search of one species does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed first protein composition (one of (i)-(iii)) and a second protein composition (one of (iv)-(viii)), consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Failure to elect first protein composition and a second protein composition consonant with Applicant's elected invention may result in a notice of non-responsive amendment.

3. **Should Applicant elect Invention I, a species restriction to one of the following is also required under 35 USC 121.** Currently, Claims 13 and 62 of this application are generic to a plurality of disclosed, patentably distinct anesthetics that prohibit proper examination of this claim. Therefore, election is required under 35 U.S.C. 121 of one anesthetic from the list consisting of the anesthetics recited in Claims 34 and 64 consonant with Applicant's elected invention for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

In the instant case, each anesthetic species is of materially different structure, has a different mode of action and non-identical effects than the other compounds. A search for halothane would not be co-extensive with a search for sodium pentobarbitone. Further, a reference rendering chloral hydrate as anticipated or obvious over the prior art would not necessarily also render xenon as anticipated or obvious over the prior art. Similarly, a finding that urethane was novel and unobvious over the prior art would not necessarily extend to a finding that desflurane was also novel and unobvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one species does not necessarily overlap with that of another species, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated is proper.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed anesthetic for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Failure to elect an anesthetic consonant with Applicant's elected invention may result in a notice of non-responsive amendment.

Should Applicant elect Invention II, a species restriction is required under 35 U.S.C. 121. Currently, Claim 45 is generic to the reaction chamber in which the method step of contacting a test substance with a first and second protein is performed. Applicant is required to elect a single disclosed reaction chamber in which the method step of contacting a test substance with a first and second protein is performed for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, specifically:

i) wherein the step of contacting is done *in vitro*, or

ii) wherein the step of contacting is done in yeast cells.

The inventive reaction chambers are unrelated because the reaction chamber (i) is an artificial, non-living system that approximates, but is not identical to, normal cellular physiological conditions; whereas, the reaction chamber (ii) is an intact, living yeast cell. The method steps to perform a protein-protein binding reaction *in vitro* are distinctly different than the method steps of culturing yeast cells simultaneously exposed to different chemical compounds and expressing the desired proteins.

A reference rendering a protein-protein binding assay performed in yeast cells as anticipated or obvious over the prior art would not necessarily also render protein-protein binding assay performed *in vitro* as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed reaction chamber in which the method step of contacting a test substance with a first and second protein is performed,

even though this requirement is traversed. Failure to elect a reaction chamber consonant with Applicant's elected Invention, may result in a notice of non-responsive amendment.

Should Applicant elect Invention II, a species restriction is required under 35 U.S.C. 121. Currently, Claim 45 is generic to the method step of determining an amount of free or bound molecules that prohibit proper examination of this claim. Applicant is required to elect a single disclosed method step of determining an amount of free or bound molecules for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable, specifically:

i) wherein the step to determine said amount is performed using surface plasmon resonance as recited in Claim 60, or

ii) wherein the step to determine said amount is performed using antibodies as recited in Claim 61.

The inventive method steps are unrelated because the apparatus of (i) is materially different in design and mode of operation than, and is not disclosed as capable of use together with, the apparatus of (ii). A reference rendering an antibody binding assay as anticipated or obvious over the prior art would not necessarily also render surface plasmon resonance as anticipated or obvious over the prior art. Because these inventions are distinct for reasons given above, and because a search of one does not necessarily overlap with that of another, it would be unduly burdensome for the examiner to search and examine all the subject matter being sought in the presently pending claims and thus, restriction for examination purposes as indicated.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed method step of determining an amount of free or bound molecules, even though this requirement is traversed. Failure to elect a method step of determining an amount of free or bound molecules consonant with Applicant's elected Invention, may result in a notice of non-responsive amendment.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that

all claims are generic is considered nonresponsive unless accompanied by an election. Failure to elect species consonant with Applicant's elected invention may result in a notice of non-responsive amendment.

Should Applicant traverse on the ground that the species are not patentably distinct, Applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin K. Hill, Ph.D. whose telephone number is 571-272-8036. The examiner can normally be reached on Monday through Friday, between 9:00am-6:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER